--94. The compound according to claim 93, wherein R^1 and R^2 are both docosahexaenoic acid moieties.--

REMARKS

I. PENDING CLAIMS AND SUPPORT FOR AMENDMENTS

Upon entry of the present amendment, claims 27-93 will be pending in this application. Claims 27 and 34 have been amended to remove extraneous language to which the Examiner has raised objection. Claim 30 has been amended to use the more appropriate "which comprises" terminology with respect to the linkage between the diol oxygens and the R^1 and/or R^2 moieties. Claims 57, 59, and 66 have been amended to clarify that the inflammatory and autoimmune diseases recited are those other than rheumatoid arthritis or osteoarthritis, which are specifically recited elsewhere in the Markush grouping. Claims 65 and 66 have been amended to distinguish dyslexia from learning disabilities.

New claims 93 and 94 are supported by the specification at page 17.

No new matter has been added.

II. REJECTION UNDER 35 U.S.C. § 112, FIRST AND SECOND PARAGRAPHS

At page 3 of the Office action, the Examiner has rejected claims 27-92 under 35 U.S.C. § 112, first and second paragraphs as "failing to properly define the invention." Applicants respectfully traverse this rejection and request reconsideration and withdrawal thereof.

The Examiner recites a laundry list of terms that he does not like because he considers them to be "too broad." He then provides a stereotypical "rationale" supporting his conclusion, to the effect that the terms are too broad because: (1) they render the claims indefinite, apparently because they place "no definite limits or boundaries on the claims"; (2) they result in the claims being based on insufficient disclosure because the terms are "so broad as to read on subject matter as to which the disclosure is not enabling" or for which the disclosure provides insufficient written description.

Nowhere does the Examiner explain why any term in his laundry list creates any ambiguity or confusion, or blurs the boundaries of the claims, particularly when the claim terminology is read in light of the specification. For example, the Examiner complains about Applicants' use of the term "nutrient, drug, or other bioactive compound," in claim 27 and elsewhere, and complains about the use of each of these terms individually. However, in the very first sentence of the specification, Applicants state:

> The specification relates to the presentation of bioactives, in which term we include a drug, essential nutrient or any other compound to be administered to the human or animal body in therapy or the maintenance of health.

Moreover, the terms in the claims and in the specification are directed to those of skill in the art. The Examiner cannot seriously contend that those of skill in this art do not understand what the words "drug" or "nutrient" mean.

In addition, the specification is very clear from the very first page that the advantage of the claimed compounds is that they provide bioactive moieties or residues in a form that improves the pharmacokinetic properties of the bioactive material because the resulting structure renders the overall compound lipophilic. As a result, the drug, nutrient, or other bioactive residue can readily pass through lipid boundaries in the body. The precise nature of the bioactive compounds, while it may be of significance to the PTO's classification scheme, is not of particular significance to the precision with which Applicants have defined their claims. The claims are broad because the scope of invention to which the Applicants are entitled is broad, at least until the Examiner has presented prior art establishing the contrary. Drugs, nutrients, or other bioactive compounds as defined in the specification, attached through an oxy linkage to a 1,3-propanediol compound, which is linked through the other diol oxy group to a fatty acyl or fatty alcohol ether are within the scope of the claims. Similarly, fatty esters and fatty alcohol ethers of 1,3-propanediol occurring at one or both propanediol oxy moieties are also within the scope of the invention.

Thus, when the claims are read in light of the specification, as they must be, it is clear that one of skill in the art could easily determine whether or not a particular compound falls within the scope of the claims. This is all that is required in order to satisfy the requirements of 35 U.S.C. § 112, second paragraph. *See In re Johnson*, 194 USPQ 187 (CCPA 1977); *In re Miller*, 169 USPQ 597 (CCPA 1971).

Turning to the other terms on the Examiner's list, which appear in dependent claims, Applicants note that these terms are either defined sufficiently in the specification, or are so well known to those of skill in this art (and to whom the specification is addressed) that defining them would be superfluous. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 (Fed Cir. 1986).

For example, the term "nonsteroidal antiinflammatory drug" is widely used in the pharmaceutical industry, and is also explained, with examples, at page 19 of the specification. Protein pump inhibitors are described at page 32 of the specification, and are known to those of skill in the art. Hypolipidaemic agents are also well known in the pharmaceutical industry and are explained in the specification, with examples, at page 33. Fibrates and statins are types of hypolipidaemic agents that are well known to those of skill in the art. Diatrizoate compounds are known radiological contrast agents, as explained at page 33 of the specification. Inflammatory and autoimmune conditions other than rheumatoid arthritis or osteoarthritis are described in the specification, with examples, at pages 25 and 29. Degenerative diseases of the eye are described, with examples, at pages 27 and 29. Allergic disorders are described, with examples, at page 25 of the specification. Foods, nutritional supplements, and food additives are described at page 33 of the specification. Certainly, those of skill in the art are aware of the vitamins, described in the specification as examples of foods, nutritional supplements, and food additives. Bacteriochlorin-based drugs are described, with examples, at page 33 of the specification.

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Cachexia is well known to be a term for physical wasting away and malnutrition associated with a chronic disease. Cancer cachexia would be therefore be a wasting away or malnutrition associated with cancer.

One of the disclosed advantages of the present invention is that the compounds of the invention permit the administration of multiple bioactive agents simultaneously, e.g., wherein one or more of the fatty acid or fatty alcohol moieties is bioactive. As a result, the compounds of the invention provide an advantage in that bioactive compounds not normally presented together can be administered so as to achieve an additive effect by administering a single compound, i.e., the compound of the invention. Moreover, these bioactives may have synergistic effects, i.e., the effect of administering the compounds bioactive agents in a single compound are greater than the sum of the effects observed when the bioactive compounds are administered individually. This is the meaning of the terminology "additive to, complementary to, or synergistic with" as used in claim 35, as explained at page 1 of the specification.

Similarly, the other terms on the Examiner's list, when they are read in light of the specification, and in the context of the claims in which they appear, reasonably set out the metes and bounds of the claims to one of skill in the art. Accordingly, there is no ambiguity or indefiniteness of scope, and therefore no appropriate rejection under 35 U.S.C. § 112, second paragraph.

The Examiner has also indicated that he considers the claims are not supported by adequate written description under 35 U.S.C. § 112, first paragraph. Applicants submit that this position is also incorrect, since the claim terminology listed by the Examiner is all supported in the specification as indicated above (with respect to the definiteness of the terminology under 35 U.S.C. § 112, second paragraph). Accordingly, these claims do not add new matter to the application and are fully supported by the specification and claims as originally filed, and the Examiner's objection concerning lack of written description should be withdrawn.

Finally, with respect to the terms on his list, the Examiner alleges that "the expressions cover vast numbers of compounds many of which are not adequately described nor enabled by for the full scope thereof especially with regard to starting materials, precise reaction conditions, and so on." Applicants respectfully disagree, and submit that the present specification fully enables the scope of the claim in compliance with 35 U.S.C. § 112, first paragraph.

As Applicants explain beginning at page 33 of the specification, the methods for manufacturing the esters of the present invention are considerably milder than those necessary for the manufacture of triglycerides, but that similar processes can be used. Enzymatic processes for making the diesters of the invention are also described. Moreover, Applicants provide 51 synthesis examples for making the esters of the present claims, using a wide variety of R^1 and R^2 moieties. Applicants submit that the general description of how

the esters of the invention can be made, coupled with the 51 specific synthesis examples and the fact that the syntheses involve fairly straightforward esterifications, rather than complicated multistep syntheses, render the description more than adequate for one of skill in the art to make the full range of compounds claimed. The Examiner has not provided any facts or scientific reasoning explaining why the extensive description in the specification is insufficient in this regard. *See In re Marzocchi*, 169 USPQ 367 (CCPA 1971); *In re Dinh-Nguyen*, 181 USPQ 46 (CCPA 1974). Certainly, manipulation of recognized reaction parameters for an esterification reaction are well within the purview of one of skill in this art without the need for undue experimentation, given the extensive guidelines provided by the specification. As a result, the full scope of the claims is enabled in accordance with 35 U.S.C. § 112, first paragraph.

Accordingly, Applicants respectfully submit that the Examiner's rejections under 35 U.S.C. § 112 are inappropriate, and request withdrawal thereof.

III. THE RESTRICTION/ELECTION OF SPECIES REQUIREMENT

A. The Restriction Requirement

At pages 3-6 of the Office action, the Examiner has required restriction between the following groups of claims: Group I, claims 27-56; and Group II, claims 57-92. The Examiner alleges that these groups of claims are related as mutually exclusive species in an intermediate-final product relationship.

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Applicants elect the invention of Group I, with traverse. Contrary to the Examiner's assertions, Groups I and II are not related as intermediate-final product, as alleged by the Examiner. The claims of Group I are directed to compounds and compositions. The claims of Group II are directed to methods, not products, for treating disorders using the compounds and compositions of Group I. Accordingly, the Examiner has failed to establish that the groups are patentably distinct.

In addition to failing to establish that the inventions claimed in Groups I and II are patentably distinct, the Examiner has also failed to establish any undue burden on examination resulting from the presence of both groups of claims in a single application. Applicants have elected the product claims of Group I, directed to compounds and compositions. If these claims are found to be novel and nonobvious, then claims to methods for using these compounds and compositions must also be found to be novel and nonobvious, since it cannot have been obvious to use a nonobvious and novel compound or composition. Moreover, since the Examiner will have to search the same classes and subclasses for the method claims as he will search for the composition claims, there is no undue search burden.

Since the Examiner has failed to establish either of the prerequisites for requiring restriction, the requirement made in the Office action is improper and should be withdrawn.

B. The Election of Species Requirement

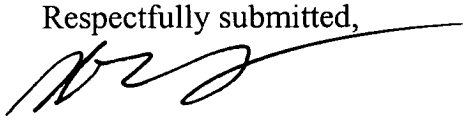
At page 5 of the Office action, the Examiner has required Applicants to elect from among the patentably distinct species alleged to be present in claim 27, without delineating

which species the Examiner believes to be patentably distinct, or even providing examples of patentably distinct species. Applicants believe that "the various species encompassed by the broad terminology encompassed by 'the residue of a nutrient, drug, or other bioactive compound of disorders of claim 27'" encompasses esters wherein both R^1 and R^2 are fatty acid acyl groups or fatty alcohol groups of 12-30 carbon atoms, since as explained in the specification, these moieties can also be bioactive residues. Accordingly, Applicants elect the species of compound wherein both R^1 and R^2 are fatty acid acyl groups or fatty alcohol groups of 12-30 carbon atoms, with traverse. If this species is not what the Examiner had in mind, then Applicants respectfully suggest that the Examiner recast the election requirement in order to make more clear which species the Examiner considers patentably distinct. Claims 27-30, 32-33, 36-38, 56, 93, and 94 are all readable on the elected species.

Applicants traverse the election requirement, however, because it is not clear from the requirement whether the Examiner intends to follow the procedures specified in MPEP 803.02, which Applicants submit is the only appropriate procedure in the present situation. If the Examiner does not intend to follow this procedure, then Applicants respectfully submit that the election requirement is improper and should be withdrawn.

Please charge any additional fees or credit any overpayment to Deposit Order Account No. 11-0855.

Respectfully submitted,



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